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| APPLICATION NO.                              | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|--|---------------|----------------------|------------------------|------------------|
| 09/589,675                                   | 06/07/2000    | Steven C. Murray     | PA1513US               | 8651             |
| 7590 04/19/2005                              |               |                      | EXAMINER               |                  |
| MARK A. HAYNES, ESQ.                         |               |                      | FARAH, AHMED M         |                  |
| HAYNES BEFFEL & WOLFELD LLP<br>P.O. B OX 366 |               |                      | ART UNIT               | PAPER NUMBER     |
|  | BAY, CA 94019 |                      | 3739                   |                  |
|  |               |                      | DATE MAILED: 04/19/200 | 5                |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
|   | 09/589,675  | MURRAY ET AL.  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | Ahmed M Farah   | 3739   |  |  |  |  |
| The MAILING DATE of this communication Period for Reply   | appears on the cover sheet w  | th the correspondence address  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR RE THE MAILING DATE OF THIS COMMUNICATIO  - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication  - If the period for reply specified above is less than thirty (30) days, a  - If NO period for reply is specified above, the maximum statutory pe  - Failure to reply within the set or extended period for reply will, by si Any reply received by the Office later than three months after the n earned patent term adjustment. See 37 CFR 1.704(b). | ON. R 1.136(a). In no event, however, may a n. a reply within the statutory minimum of thir eriod will apply and will expire SIX (6) MON tatute, cause the application to become Al                               | reply be timely filed  ty (30) days will be considered timely.  ITHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1) Responsive to communication(s) filed on 2  | <u> 4 January 2005</u> .  |  |  |  |  |  |
| 2a)⊠ This action is <b>FINAL</b> . 2b)□   | This action is non-final.   |  |  |  |  |  |
| ,—  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| 4)  | drawn from consideration. d. s/are rejected.  |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |
| 9)☐ The specification is objected to by the Exar  | miner.  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a)  | accepted or b) ☐ objected to  | by the Examiner.   |  |  |  |  |
| Applicant may not request that any objection to   |   |  |  |  |  |  |
| Replacement drawing sheet(s) including the co   |   |  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   | •  |  |  |  |  |
| 12) Acknowledgment is made of a claim for form  a) All b) Some * c) None of:  1. Certified copies of the priority docum  2. Certified copies of the priority docum  3. Copies of the certified copies of the application from the International But  * See the attached detailed Office action for a  | nents have been received.<br>nents have been received in A<br>priority documents have beer<br>ireau (PCT Rule 17.2(a)).   | Application No  received in this National Stage  |  |  |  |  |
| Attachment(s)   | <b>6</b> □ 100 1  |  |  |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>  | · -   | Summary (PTO-413)<br>s)/Mail Date  |  |  |  |  |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SI Paper No(s)/Mail Date  | ' _ <del></del>   | nformal Patent Application (PTO-152)   |  |  |  |  |

#### **DETAILED ACTION**

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 9, 11-14, 22, 23, 27 and 33 are again rejected under 35 U.S.C. 102(b) as being anticipated by Kosa U.S. Patent No. 4,695,697.

As to claims 1, 9, 22, and 26, Kosa discloses a laser delivery system for irradiating tissue (see column 6, lines 45-54), the system comprising:

a fluorescent element **22** positioned to receive a pump radiation having a narrow spectral band (see Fig. 1) and responsively generate radiation by spontaneous emission, the spontaneously emitted radiation being diffuse (see Figs. 2-8) and having a peak emission outside the pump radiation (see column 4, lines 37-45); wherein the fluorescent element is adapted to deliver at least a portion of the diffuse emitted radiation toward a tissue target.

As to claims 2-3 and 5, the fluorescent material includes fluorescent ions and is selected from a group consisting of a solid-state crystal and glass (see column 6, lines 55-66)

As to claim 11, the pump radiation is generated by an Nd:YAG laser. Neodymium YAG lasers are commonly operated at the principle, 2<sup>nd</sup> harmonic generation (frequency-doubled), 3<sup>rd</sup> harmonic generation, etc.

As to claims 12 and 23, the pump radiation is delivered to the fluorescent element through an optical fiber 20 as presently claimed.

As to claim 14, the optical fiber 20 comprises a reflective coating 33 (conventional fiber cladding film) that is transparent to the pump radiation to reflect/direct the emitted radiation toward the target tissue as presently claimed.

As to claim 27, Kosa teaches that his apparatus has general utility for various systems employing laser beam energy. He further teaches that the tip assembly is adapted for use in combination with laser devices for a variety of medical procedures such as angioplasty, arteriosclerosis, etc. (see column 4, line 45 to column 5, line 2).

As to claim 33, a portion of the spontaneously emitted radiation from the fluorescent element is reflected back to the optical fiber. The boundary between the optical fiber core and cladding material in turn reflects at least a portion of said reflected radiation back to the target tissue. Hence the delivery system of Kosa provides the claimed limitation.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 28-32 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Kosa in view of Anderson et al. U.S. Patent No. 5,735,844.

Although Kosa teaches that his apparatus is used for variety of medical procedures (see column 4, line 45 to column 5, line 2), he does not particularly teach it is used for treating tumor, pigmented lesion, or removing hair. He further fails to teach that the target tissue is cooled.

Anderson et al. teach a medical treatment device comprising: an Nd:YAG laser (see column 9, line 6) for generating a treatment energy; an optical fiber adapted to deliver the treatment/laser energy to a delivery tip (see Fig. 2A), the delivery tip comprising a cooling unit and a tissue contact tip 46 for simultaneously directing the treatment energy to the target tissue and cooling the tissues being treated.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Kosa in view of Anderson et al to cool the tissue during treatment so as to avoid undesired injury/heating of the tissue and/or to reduce discomfort to the patient. It would have further obvious to use the device for treating tumors, pigmented lesions, and/or hair removal.

### Allowable Subject Matter

Claims 6-8, 10, 15-21 and 26 are allowed.

As to claims 6-8, the prior art of record do not teach or suggest a device for irradiating tissue as claimed, the device comprising a fluorescent element positioned to receive pump radiation having a narrow-spectral band and responsively generate

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radiation by spontaneous emission, the spontaneously emitted radiation being diffuse and having peak emission outside said narrow spectral band: and the fluorescent element being adapted to deliver al least a portion of the diffuse emitted radiation toward a tissue target, wherein the fluorescent element comprises a liquid fluorescent dye solution.

As to claim 10, the prior art of record do not teach or suggest a device for irradiating tissue as claimed, the device comprising a diffuse reflector for redirecting at least a portion of a diffuse emitted radiation toward a tissue target, wherein the diffuse reflector has a frustro-conical shape.

As to claims 17-22, the prior art of record do not teach or suggest a device for irradiating tissue as presently claimed, the device comprising a redirector for redirecting at least a portion of the diffuse, spontaneously emitted radiation toward a target tissue, wherein the redirector comprises a waveguide including a reflective entrance face and reflective walls, the entrance face having a substantially transmissive aperture formed therein for admitting pump radiation into the waveguide.

Claim 4 is again objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### Response to Arguments

Applicant's arguments filed on January 24, 2005, have been fully considered but they are not persuasive. The applicant argues that in Kosa, no interaction of diffuse

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radiation with target tissue is mentioned and the fluorescent radiation is not directed to the target tissue. Applicant further argues that even if the fluorescent radiation of Kosa is directed to the target tissue, it lacks sufficient fluence for therapeutic effect as recited in the amended claims.

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In response to the first argument, again the examiner's position is that due to the structure of the fluorescing element 22, at least a portion of the emitted fluorescent radiation is inherently directed to the target tissue. In response to the second argument, the applicant's written description, in particular page 6, lines 16-22, fails to clearly disclose, teach or suggest the fluence of diffuse radiation that is considered to have a sufficient therapeutic effect as recited in the amended claims. Therefore, the added limitation is considered as being indefinite and would not place the claims in condition for allowance.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (571) 272-4765. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM...

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

> Ahmed M Farah Primary Examiner Art Unit 3739

April 12, 2005.